

C. Remarks

Claims 1-18 are pending, with claims 1, 11, 15, and 17 being independent. Claims 1-10, 15, and 16 are allowed. Reconsideration of pending claims 11-14, 17, and 18 is respectfully requested.

Claims 11, 12, and 17 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Wright et al. (J. Med. Chem. 2001, 44:3187) ("Wright"). Applicants respectfully traverse this rejection.

Applicants respectfully reiterate their prior arguments that the aqueous phase from which Wright's compound 17 is obtained contains reagents that are not suitable for a pharmaceutical composition (*see* Wright at paragraph 3 (titled step 2), page 3192). Further to Applicants' arguments previously presented, one skilled in the art would know that both potassium hydrochloride (KOH) and dichloromethane are not suitable to be present in a pharmaceutical composition. Ingestion of potassium hydroxide can produce violent pain in the throat and epigastrium, hematemesis, and stricture of the esophagus, which may be fatal (*see* Merck Index (12th ed., 1996) at p. 1315). Among other hazards, dichloromethane is thought to be carcinogenic (*see* Merck Index (12th ed., 1996) at p. 1035). Moreover, the pH ranges of the solutions containing Wright's compound 17 prior to its recovery, namely 3 and 11, are both unacceptable pHs for an aqueous pharmaceutical composition, as one skilled in the art would know. Therefore, Applicants respectfully submit that they have met the burden of providing evidence that that aqueous phase from which compound 17 is obtained contains reagents that are not suitable for a pharmaceutical composition, and request that the anticipation rejection be withdrawn.

Claims 11 and 17 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Bierer et al. (U.S. 5,741,926) (“Bierer”). Applicants have amended these claims and respectfully submit that, as amended, Bierer compound AC does not fall under the claimed genus. Therefore, Applicants respectfully request withdrawal of the anticipation rejection.

Claims 11-14, 17, and 18 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Bierer. Applicants respectfully traverse this rejection. Applicants respectfully reiterate their prior arguments and disagree with the Examiner’s assertion that the “generic structure of formula III [of Bierer] teaches the instant claims with sufficient particularity that the compounds of the instant invention would have been *prima facie* obvious” (*see* Office Action at p. 5).

To establish a *prima facie* case of obviousness, three criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference(s) must teach or suggest all the claim limitations (*see* MPEP § 2143). To satisfy the first criterion, the prior art must suggest the desirability of the claimed invention (*see* MPEP § 2143.01). The fact that a reference can be modified, or that the claimed invention is within the capabilities of one skilled in the art, is not sufficient to establish *prima facie* obviousness (*Id.*).

Formula III of Bierer is a broad genus claim that provides for numerous possible substituents at positions 2, 3, 4, 5, and 6 of the phenyl ring (R₁-R₅, respectively) (*see* Bierer at col. 11, l. 4-25). As noted by the Examiner (*see* Office Action at p.4), Bierer

does not teach the compounds recited in claims 12-13 and 18 of the present application. Moreover, the teachings of Bierer do not take into account the important notable features of the claimed invention – (1) having the W/Y substituent shown in claims 11 and 17 at the ortho position (position 2) of the phenyl ring, and (2) limiting the possible substituents at this position to COOH or 5-tetrazolyl. As shown by the data presented in the Declaration Under 37 C.F.R. § 1.132, filed May 11, 2007, both the choice of substituent, as well as its placement in the ortho position, are important features of the claimed invention. According to the MPEP, “[i]f one of ordinary skill in the art is able to ‘at once envisage’ the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be ‘at once envisaged.’” (See MPEP § 2131.02). Based upon the teachings of Bierer, one of skill in the art would not at once envisage the claimed compounds/chemical formula.

Applicants respectfully submit that Bierer provides no suggestion or motivation to modify the reference to reach the claimed invention, nor does it teach or suggest all the claim limitations. Therefore, for at least the reasons set forth above, Applicants respectfully submit that the claimed invention is patentable over Bierer and request that the 35 U.S.C. §103(a) rejection be withdrawn.

In view of the foregoing remarks, Applicants respectfully submit that all rejections set forth by the Examiner have now been overcome. Accordingly, Applicants respectfully request allowance of the pending claims and prompt passage of the application

to issue. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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